



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,513	08/22/2001	Harlan Edgar Shannon	X-10576A	9165

25885 7590 03/12/2003

ELI LILLY AND COMPANY  
PATENT DIVISION  
P.O. BOX 6288  
INDIANAPOLIS, IN 46206-6288

EXAMINER
----------

CRIARES, THEODORE J

ART UNIT	PAPER NUMBER
----------	--------------

1617

DATE MAILED: 03/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/935,513

Applicant(s)

SHANNON ET AL.

Examiner

Theodore J. Criares

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 August 0202.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-44, 60-67 and 81-91 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-44, 60-67 and 81-91 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Art Unit: 1617

## **CLAIMS 1-44, 60-67 AND 81-91 ARE PRESENTED FOR**

### **EXAMINATION**

#### **DOUBLE PATENTING REJECTION**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-44, 60-67 and 81-91 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,4 and 5 of U.S. Patent No. 5,972,932. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims encompass compositions which are similar or are obvious. Specifically, claims 1, 9, 10 and 13 exemplify the obvious type double patenting rejection. Claims 1 and 10 of the application recite the combination of olanzapine and a Drug Useful in the Treatment of Pain.(claim 1) and claim 10 which depends from claim 1 recites the Drug Useful in the Treatment of pain to be an opioid. compound. Claim 1 of ' 932 recites olanzapine and an opioid. The difference between the application claims and '932 is that the preamble in the

Art Unit: 1617

application is drawn to compositions for the treatment of pain and the compositions of '932 are drawn to anesthetic compositions since the preamble in this instance has been given weight as olanzapine has not been known for this treatment recited in the preamble. Therefore, the '932 claims are deemed generic to the claims of the application since the intended use of the compositions is unobvious. See *Eli Lilly & Co. vs. Barr Labs, Inc.* 251 F.3d 955; 58 U.S.P.Q.2d 1865 (Fed. Cir. 2001)

Similarly claims 9 and 13 of the application are obviated under 35 U.S.C. 103(a) since they read on claims 4 and 5 of the '932 patent as follows:

'932		Application	
Compound recited		Compound recited	
Claim 4	Morphine	Claim 9	Morphine
Claim 5	buprenorphine	Claim 13	buprenorphine

Applicants are advised that additional combination may be present in the claims.

The previous allowance and rejections of claims 1-44, 60-67 and 81-91, respectively, are withdrawn.

#### **REQUEST FOR SUPPLEMENTAL DECLARATION**

In accordance with 37 CFR 1.175(b)(1), a new reissue oath/declaration under 37 CFR

1.175(b)(1) must be received before this reissue application can be allowed.

All claims are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251. See 37 CFR 1.175. The nature of the defect is that the declaration fails to set forth a specific errors as required. The present declaration only sets forth errors in general and is therefore defective.

Art Unit: 1617

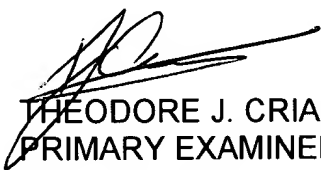
Receipt of an appropriate new supplemental oath/declaration under 37 CFR 1.175(b)(1) will overcome this rejection under 35 U.S.C. 251.

It is also suggested that applicant telephone the examiner to resolve the issue of Double Patenting to accelerate prosecution of the application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is 308-4607. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-6897 for regular communications and N/A for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.



THEODORE J. CRIARES  
PRIMARY EXAMINER  
ART UNIT 1617

tjc  
March 6, 2003

Application/Control Number: 09/935,513

Art Unit: 1617

Page 5